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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
03/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,072	HEIL ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 25-66* is/are pending in the application.

4a) Of the above claim(s) *33-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23,25-32 and 48-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20071203*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 4-7, 9, 13, 15, 18, 19, 21, 22, 27, 28, 30, 48, 49, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Kroll et al. (US 6,282,444, hereinafter "Kroll").

3. In regards to claims 1, 18, 21, and 48, Kroll discloses a device that comprises a lead body (74 and 76), a cardiac electrode capable of subcutaneous non-intrathoracic placement for cardiac monitoring and cardiac stimulation (col. 3, line 46 and col. 12, line 13), one or more conductors within the lead body (col. 5, line 53), a pharmacological agent provided along an exterior surface of the lead body/can (col. 11, line 65), and a driving arrangement to drive the agent from the exterior surface to subcutaneous tissue (col. 11, line 58). Please note that, because the biocide is applied "surrounding the cardiac stimulation device" and the "cardiac stimulation device" comprises the housing and lead, Kroll's device anticipates the claim limitations. Additionally, claim 55 does not

require that the first and second pharmacological agents are different drugs. Therefore, the "first pharmacological agent" is the portion of the biocide that surrounds the lead, and the "second" agent is the agent that surrounds the can.

4. In regards to claims 2, 19, and 49, the driving arrangement comprises an electrode on the lead body/can (128, 130 and 138) that is adapted to provide electrophoresis because it provides an electric field (i.e. the electrodes "are adapted to provide electrophoresis", regardless of whether there is an ionic substance present).

5. In regards to claim 4, the electrode is an electrode array (130 and 138).

6. In regards to claim 6, the pharmacological agent provides therapeutic treatment systemically as well as locally (col. 11, line 50), thusly including a dissection path.

7. In regards to claim 7, the agent is provided over a plurality of arbitrarily chosen portions of the surface of the lead body.

8. In regards to claim 9, the agent is provided at the "collar" electrodes (130 and 138).

9. In regards to claims 13, 27 and 28, the agent is provided in a coating of at least 25% because the agent "surrounds" the device.

10. In regards to claims 15, 30, and 52, the agent is an antibiotic (col. 11, line 65).

11. In regards to claims 22, the lead and can produce an electric potential between the two (136 and 142).

12. Claims 1, 2, 4-7, 11, 16-19, 21, 22, 25, 31, 32, 48, 49, 53, and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by Darvish et al. (US 7,190,997, hereinafter "Darvish").

13. In regards to claims 1, 18, 22, and 48, Darvish discloses a device that comprises a lead body (104), a cardiac electrode capable of subcutaneous non-intrathoracic placement for cardiac monitoring and cardiac stimulation (col. 5, line 59), one or more conductors within the lead body (Figs. 3A-E), a pharmacological agent provided along an exterior surface of the lead body/can (col. 5, line 8; col. 6, line 30; col. 13, line 65, col. 15, line 12, and col. 16, line 23), and a driving arrangement to drive the agent from the exterior surface to subcutaneous tissue (col. 4, line 67).

14. In regards to claims 2 and 21, the driving arrangement comprises an electrode supported by the lead body (182).

15. In regards to claim 4, the electrode is an electrode array (col. 14, line 32).

16. In regards to claims 5, 19 and 49, the arrangement provides electrophoresis (col. 6, line 56).

17. In regards to claim 6, the agent provides therapy to an area localized to a dissection path (col. 15, line 15).

18. In regards to claim 7, the agent is provided over a plurality of arbitrarily chosen portions of the surface of the lead body.

19. In regards to claims 11 and 25, the lead comprises a porous region containing pharmacological agent (col. 15, line 56).

20. In regards to claims 16, 17, 31, 32, 53, and 54, Darvish's device provides steroids (col. 25, line 65) and an agent that promotes hemostasis (col. 25, line 55).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 55, 58, and 64 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kroll. Kroll discloses the essential features of the claimed invention, including providing a first and second pharmacological agents (the agents are not claimed as being different, so the first agent is the agent that surrounds the lead and the second agent is the agent that surrounds the can), and providing driver circuitry separate from the pacing device (col. 12, line 18),

inherently disclosing a "detachable coupling'. Alternatively, it is well known in the art to provide separate devices with detachable couplings to allow the devices to be implanted separately and later coupled to minimize implantation trauma. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Kroll's device with a detachable coupling to provide the predictable results of allowing the devices to be implanted separately and later coupled to minimize implantation trauma.

24. Claims 55, 56, 65, and 66 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Darvish. Davrish discloses the essential features of the claimed invention, including providing multiple agents (col. 9, line 43) and providing a separate driving means (col. 12, line 40-col. 13, line 34). Because the means are separate, they are detachably coupled, such as the embodiment at col. 12, line 64. Alternatively, it is well known in the art to provide separate devices with detachable couplings to allow the devices to be implanted separately and later coupled to minimize implantation trauma. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Darvish's device with a detachable coupling to provide the predictable results of allowing the devices to be implanted separately and later coupled to minimize implantation trauma.

25. Claims 3, 8, 10, 12, 14, 20, 23, 26, 29, 50, 51, 53, 57, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll (or Darvish). Kroll (or Darvish) discloses the essential features of the claimed invention except for a sonophoresis

driving mechanism; a pharmacological agent impregnated in a membrane coating; a pharmacological agent infused in a porous doped polymeric structure; or an analgesic/anesthetic agent. It is well known in the art to provide implantable devices with sonophoresis driving mechanisms to provide deeper penetration of non-ionically charged medications; pharmacological agents impregnated in membrane coatings to provide an easily manufactured device with medication delivered over a large surface area of the device; pharmacological agents infused in porous doped polymeric structures to provide slow and controlled release of a drug over a long period of time; and analgesic/anesthetic agents to provide a less painful recovery from implantation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Kroll's (or Darvish's) invention with a sonophoresis driving mechanism to provide the predictable results of deeper penetration of non-ionically charged medications; a pharmacological agent impregnated in a membrane coating to provide the predictable results of an easily manufactured device with medication delivered over a large surface area of the device; a pharmacological agent infused in a porous doped polymeric structures to provide the predictable results of slow and controlled release of a drug over a long period of time; and an analgesic/anesthetic agent to provide the predictable results of a less painful recovery from implantation.

26. Claims 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll (or Darvish). Kroll (or Darvish) discloses the claimed invention, including various configurations of the medication/pacing control housing(s) but does not disclose expressly the driver provides a phoresis power signal to the implanted device, wherein

the control signal is DC, AC, or AC with a DC offset. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the driver as taught by Kroll (or Darvish) with the various control signals because applicant has not disclosed that AC, DC or AC with DC offset provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the control signal as taught by Kroll (or Darvish) because both systems signal to the drug delivery module when medication is needed. Therefore, it would have been an obvious matter of design choice to modify the control signals as disclosed Kroll (or Darvish) to obtain the invention as specified in the claims.

Response to Arguments

27. Applicant's arguments filed 1/3/2008 have been fully considered but they are not persuasive. Applicant argued that Kroll fails to anticipate the claimed subject matter because Kroll is lacking a disclosure of subcutaneous, non-intrathoracic lead placement, and a pharmacological agent provided along as least a longitudinal portion of an exterior surface of the lead body. However, Kroll includes inherent disclosure of these features. For instance, even if Kroll did not provide the explicit disclosure of "transthoracic pacing," Kroll's intracardiac electrodes are capable of subcutaneous, non-intrathoracic placement because they are of a size and material capable of placement between the skin and ribs. As the rejected claims are apparatus claims, the "subcutaneous, non-intrathoracic" limitation does not impart any structural detail that is

not present in the Kroll reference. In regards to the "pharmacological agent provided along at least a longitudinal portion of an exterior surface of the lead body" limitation, Kroll discloses that a biocide "surrounding the cardiac stimulation device" can be provided. As indicated in the previous "Office Action," the cardiac stimulation device includes both the can and the lead. Even if the lead is not considered part of the device, the biocide is "along at least a longitudinal portion of an exterior surface of the lead body" over the portion of the lead that passes through the biocide that surrounds the can.

28. Applicant further argued that Kroll lacks a disclosure of phoresis delivery. However, referring to Fig. 4 and column 8, line 66 to column 9, line 53, Kroll describes a phoresis method using DC current, which improves the delivery of the biocide described at column 11, line 58 (please note vectors 136 and 142, distinct from normal pacing operations). It is further noted that "phoresis" is merely a suffix meaning "delivery" (*see* claims 3 and 5). As such the mere act of coating the can with biocide is arguably "phoresis."

29. In regards to the Darvish reference, Applicant argued that the Darvish lead is not disclosed as being configured for subcutaneous, non-intrathoracic placement. Examiner contends that the electrodes are inherently capable of placement in this manner because they are of a size and material capable of placement between the skin and ribs. The "subcutaneous, non-intrathoracic" limitation does not impart any structural detail that is not present in the Darvish reference.

30. Applicant further argued that Darvish is lacking disclosure of a pharmacological agent along a longitudinal portion of the lead body or can. For instance, Applicant argued that a pharmacological agent integral with a linear electrode does not necessarily anticipate a source *along* a longitudinal portion because the source could be a point or a ring. However, even if the agent is provided from a point or ring, the point or ring traverses some longitudinal portion because it cannot have zero width. Additionally, Darvish discloses that "the catheter may be drug-eluting over a portion of its length," (col. 16, line 23) clearly disclosing an agent "provided along at least a longitudinal portion." Darvish further discloses that delivery can be from the can of the stimulator because the can is the return electrode (col. 13, lines 64-67), and the electrode is drug-eluting (col. 5, lines 7-10).

Conclusion

31. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Michael Kahelin/
Examiner, Art Unit 3762